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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY, DOCKET NO.	CONFIRMATION NO.
09/714,602	11/16/2000	David William Holden	RPMS 101 CON(3)	4552

7590

06/13/2002

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/13/2002

08

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,602

Applicant(s)

HOLDEN, DAVID WILLIAM

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 57-86 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 3 and 57-86 are subject to restriction and/or election requirement.

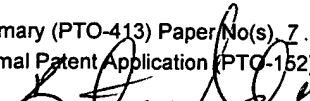
Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 7.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: 

DETAILED ACTION

Receipt is acknowledged of applicants' response to a previous Oral Restriction Requirement, filed 5/17/02 as Paper No. 6. However, following discussions with applicants' representative, Patrea Pabst, the examiner has determined that a new restriction requirement is needed that conforms to those groups previously examined in the issued parent applications. The following Written Restriction Requirement is intended to provide applicants sufficient time to consider a response in light of previously examined and issued claims and new claims that have not been previously examined (e.g. obviousness double patenting, etc.). Also, upon further review of the specification and claims 80-85, it has been determined that claims 80-85 encompass inventions that are patentably distinct and that would require a burdensome search on the part of the examiner in order to examine the different inventions as part of a single group.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 3, 57-79 and 86, drawn to methods for identifying a mutant microorganism having a reduced adaptation to a particular environment, methods of identifying the mutant gene, the identified microorganism and the identified gene, classified in class 435, subclasses 6, 29, 252.3; class 536, subclass 23.1.
- II. Claims 80-85, drawn to a non-human animal containing a plurality of mutant microorganisms wherein each mutant microorganism contains a different marker sequence, classified in class 800, subclass 8; class 435, subclass 252.3.

- III. Claims 80-83, drawn to an animal cell culture containing a plurality of mutant microorganisms wherein each mutant microorganism contains a different marker sequence, classified in class 435, subclasses, 252.3, 325.
- IV. Claims 80-81, drawn to a plant containing a plurality of mutant microorganisms wherein each mutant microorganism contains a different marker sequence, classified in class 800, subclass 295; class 435, subclass 252.3.
- V. Claims 80-81, drawn to a plant cell culture containing a plurality of mutant microorganisms wherein each mutant microorganism contains a different marker sequence, classified in class 435, subclasses 410, 252.3.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups II-V and the methods of Group I are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions of Group I can be used for different processes. For example, the compositions could be used for identification of a mutant microorganism that shows an *increased* adaptation to a particular environment (e.g. increased resistance to an antibiotic for microbial cells in an organism).

The products of Groups II-V and the mutant microorganisms and genes of Group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the

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subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of Groups II-V is drawn towards a composition comprising a plurality of mutant microorganisms, with no limitation that the plurality of microorganisms comprise microorganisms that display a reduced adaptation to living in a particular environment (e.g. in the animal, plant, plant cell culture or animal cell culture of Groups II-V). Thus, the combination of a plurality of mutants and animal, plant, plant cell culture or animal cell culture of Groups II-V do not require the particulars of the subcombination (i.e. a mutant microorganism or gene having a reduced adaptability to a particular environment) for patentability. For example, an animal comprising a plurality of microorganisms comprising only mutations in genes that confer an increased capability of survival in particular environments would be patentably distinct from an animal comprising only a single such mutant microorganism. The subcombination (i.e. the mutant microorganism or identified gene of Group I) has separate utility such as use in generating an attenuated microorganism for use as a vaccine. Thus, the products of Group I and the products of Groups II-V are patentably distinct.

Inventions of Groups II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together. Also, the different products of the different groups (i.e. animal, plant, animal cell culture and plant cell culture) have different modes of operation in that the different products are structurally, chemically and biologically

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distinct (e.g. animal versus plant, cell culture versus a living, multicellular organism). Therefore, the different products of Groups II-V are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, the nonpatent literature search required for each different Group is not required for the other Groups (e.g. plants versus animals, cell culture versus whole organisms, methods of identifying genes), restriction for examination purposes as indicated is proper.

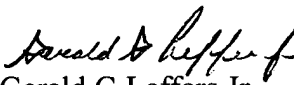
A telephone call was made to Patrea Pabst on 6/11/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
June 11, 2002